



A REPORT
TO THE
MONTANA
LEGISLATURE

PERFORMANCE AUDIT

Childhood Immunization Requirements in Montana

*Department of Public Health and
Human Services*

MAY 2014

LEGISLATIVE AUDIT
DIVISION

13P-07

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PERFORMANCE AUDITS

Performance audits conducted by the Legislative Audit Division are designed to assess state government operations. From the audit work, a determination is made as to whether agencies and programs are accomplishing their purposes, and whether they can do so with greater efficiency and economy.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Members of the performance audit staff hold degrees in disciplines appropriate to the audit process.

Performance audits are performed at the request of the Legislative Audit Committee which is a bicameral and bipartisan standing committee of the Montana Legislature. The committee consists of six members of the Senate and six members of the House of Representatives.

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May 2014

The Legislative Audit Committee
of the Montana State Legislature:

This is our performance audit of Childhood Immunization Requirements managed by the Public Health and Safety Division of the Department of Public Health and Humans Services.

This report provides the Legislature information about the immunization requirements for attendance at child care facilities, preschools, and elementary schools as well as the use of Montana's immunization registry, imMTrax.

This report includes recommendations to ensure immunization compliance at all preschools, and to more actively monitor immunization compliance at child care facilities and elementary schools. Additionally, it includes recommendations addressing data quality protection, guidance for use of imMTrax, and aligning Montana's immunization requirements with current standards of care.

A written response from the department is included at the end of the report. We wish to express our appreciation to department personnel for their cooperation and assistance during the audit.

Respectfully submitted,

/s/ Tori Hunthausen

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MONTANA LEGISLATIVE AUDIT DIVISION

PERFORMANCE AUDIT

Childhood Immunization Program

Department of Public Health and Human Services

MAY 2014

13P-07

REPORT SUMMARY

Montana is currently and historically ranked among the lowest states for the immunization coverage rate for children 19-35 months old. Montana's young children could be better protected against vaccine preventable diseases by aligning state immunization requirements with Centers for Disease Control and Prevention recommendations, monitoring preschool immunization activity, improving verification and reporting of immunization records for schools, and providing more statutory guidance for the use of the state's immunization registry.

Context

The Montana Immunization Program is part of the Communicable Disease Control and Prevention Bureau within the Public Health and Safety Division of the Department of Public Health and Human Services (department). Most of its \$3 million annual budget is funded from federal sources. The Immunization Program has 10 FTE and affects in some way every child in every county of the state through the immunizations they and their contemporaries receive. Montana has a population of nearly 61,000 children under the age of 5. There are an additional 11,700 kindergartners and more than 66,000 elementary school attendees that are most directly affected by state immunization requirements.

Historically, Montana has ranked either last-or among the lowest-of the states in immunization coverage for 19-35 month old children.

In Montana, there are lists of age-appropriate immunizations that generally all children must receive prior to attending a Montana child care, preschool, and school located in state law and administrative rule. This audit focused on determining if the department effectively enforces child care facility, preschool, and elementary school compliance with immunization requirements.

Results

Audit work found that Montana's existing immunization requirements for various facilities do not align with current standards of care for immunizations to protect against vaccine preventable diseases.

We also found no monitoring of preschool immunization requirement compliance by the department, except for preschools that are run in combination with a licensed or registered child care.

Audit work identified that while the department does monitor child care facility compliance with immunization requirements, improvements could be made to better ensure children in these settings are protected against vaccine preventable diseases. These include following up with children reported as noncompliant with requirements and changing the selection process of child care facilities for assessment.

While the department annually collects data from schools regarding the immunization status of their students, we found improvements could be made such as more consistent compilation and verification of

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data submitted by the schools to better protect elementary school attendees.

This audit also focused on the efficient and effective use of Montana's Immunization Registry (imMTrax), which is designed to make immunization requirement tracking and related activities more efficient and effective through centralized data storage and access. We identified several issues affecting the use of imMTrax, including a lack of statutory guidance regarding the sharing of information within the system, and the need for improved controls to ensure data within the system is accurate and reliable.

Recommendation Concurrence	
Concur	9
Partially Concur	1
Do Not Concur	0
Source: Agency audit response included in final report.	

Chapter I – Introduction

Introduction

Protecting the public against vaccine preventable diseases is a well-established role for the Department of Public Health and Human Services (department). A long standing foundation of this effort is the required immunization of children against certain diseases prior to their attendance at child care, preschool, and school.

The Montana Immunization Program is part of the Communicable Disease Control and Prevention Bureau within the Public Health and Safety Division. Most of its \$3 million annual budget is funded from two federal sources; they are the Vaccines for Children (VFC) program and Section 317 of the Public Health Service Act. VFC provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Section 317 is administered by the Centers for Disease Control and Prevention (CDC) and provides grants to states for vaccine purchase, outreach, and disease surveillance programs. The Immunization Program has 10 FTE and affects in some way every child in every county of the state through the immunizations they and their contemporaries receive.

A goal identified in the Public Health and Safety Division's current Strategic Plan is to, "Enforce public health laws and regulations and promote and protect health." One strategy identified to reach this goal is, "Enforce public health laws and regulations including...immunization requirements and ensuring valid medical exemptions to immunization requirements."

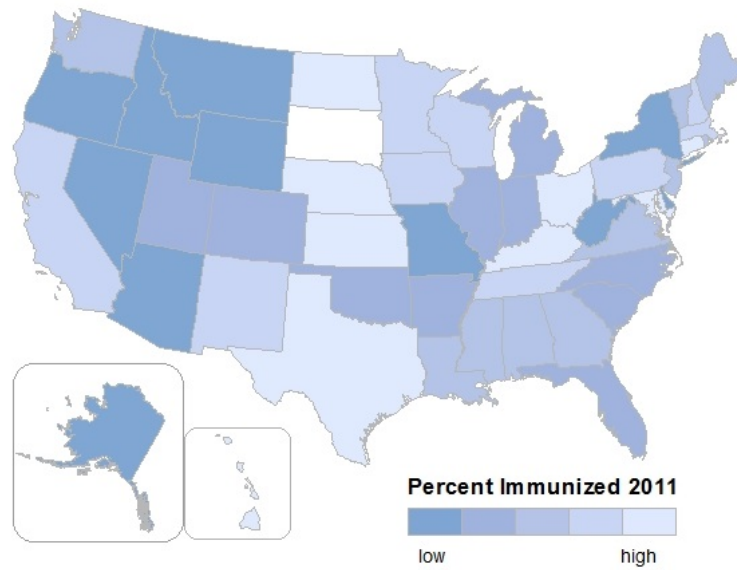
Montana Immunization Coverage Low Among States

The CDC sets the childhood immunization schedule based on recommendations from the Advisory Committee on Immunization Practices (ACIP)—a group of medical and public health experts. This schedule is adopted by the American Academy of Pediatrics and the American Academy of Family Physicians. To develop comprehensive recommendations for each vaccine, ACIP works throughout the year, reviewing available data on new and existing vaccines.

In 2013, the ACIP recommended schedule included immunization against 14 harmful and potentially deadly diseases through a series of more than 30 different shots between birth and age 6. The diseases this immunization schedule protects against includes chicken pox, diphtheria, Haemophilus influenzae type b, Hepatitis A, Hepatitis B, influenza, measles, mumps, pertussis, pneumococcus, polio, rotavirus, rubella, and tetanus. See Appendix A for more details on the diseases, immunizations, and time frames recommended for the immunizations.

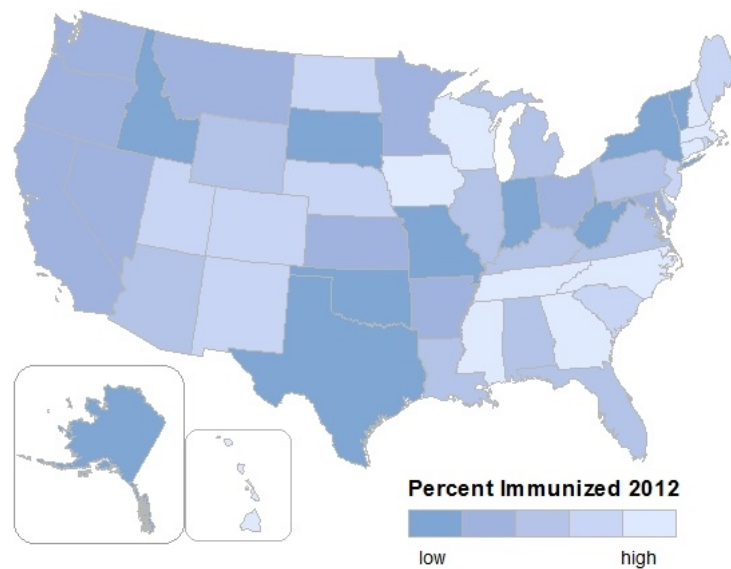
In order to gauge the public's protection against some of these vaccine preventable diseases, the CDC measures the percentage of individuals in the country that have received the ACIP recommended immunizations. The CDC uses a random survey of the parents and guardians of 19- to 35-month-olds regarding their child's immunization status, which is then verified with the child's health care provider. Montana currently ranks among the lower states in this "immunization coverage rate" for 19-35 month old children. In 2012 there were approximately 18,000 children in this age group in the state. Historically, Montana has ranked either last-or among the lowest-of the states in immunization coverage for this group but Montana's ranking has improved. In 2011, Montana's coverage rate was 59.6 percent and the state ranked 47 of the 49 states reporting. In 2012, Montana's rate increased to 66.5 percent and our ranking moved to 35 of the 50 states reporting. This change is reflected in the following maps, which show state immunization coverage rates for children 19-35 months old for 2011 and 2012.

Figure 1
State Immunization Coverage Rates for Children 19-35 Months Old
 2011



* No Data Available for South Dakota

State Immunization Coverage Rates for Children 19-35 Months Old
 2012



Source: Compiled by the Legislative Audit Division from Centers for Disease Control and Prevention's records.

Vaccine preventable diseases are not common in this country but do persist around the world and outbreaks can occur in the United States. For example, there have been

outbreaks of pertussis in various parts of Montana for the past three years. In 2011, the CDC reported 222 cases of measles in the United States, the highest number in 15 years. Because of these kinds of risks, public health experts stress that immunization coverage should be increased to prevent the resurgence of vaccine preventable diseases.

The public health concerns regarding nonimmunized children go beyond the facilities they attend. In addition to the direct protection of individuals who are vaccinated, vaccines also protect the community by decreasing the spread of infectious agents. For diseases spread through person-to-person contact, a high level of immunization in a community may disrupt the transmission of disease, thus protecting those who have not been immunized or who did not respond to the immunization. This indirect protection is called “herd immunity.”

Audit Objectives and Scope

The Legislative Audit Committee prioritized a childhood immunizations performance audit for fiscal year 2013. Based on our initial audit assessment of the immunization program activities, we developed two audit objectives. To determine if the department:

1. Effectively enforces child care facility, preschool, and elementary school compliance with existing immunization requirements.
2. Has controls in place to ensure efficient and effective use of Montana’s immunization registry (imMTrax) in order to protect public health and safety.

Those at greatest risk for missing an immunization are children younger than age 6, when the majority of immunizations are recommended to occur. Therefore, our assessment focused on children’s immunizations, specifically from birth to the beginning of school. The data reviewed in the audit is from calendar years 2010-2013.

Audit Methodologies

To address our objectives, we conducted the following audit work:

- ♦ Interviewed staff at the department, local health departments, and schools.
- ♦ Interviewed staff of other state immunization programs.
- ♦ Reviewed survey response data of local health department staff. Of 53 possible respondents, 42 (79 percent) survey recipients initiated the survey, and 36 (68 percent) finished the entire survey.
- ♦ Reviewed immunization compliance data of child care facilities and schools.
- ♦ Reviewed processes of the immunization registry (imMTrax).
- ♦ Reviewed contracts and deliverables between the department and local health departments.

- ♦ Reviewed the school reporting system.
- ♦ Reviewed federal and state laws and rules related to immunizations.

Area for Further Study

The CDC indicates that a significant barrier to achieving a more fully immunized population is the lack of dependable and centralized records. Consequently, all states are working toward achieving a complete immunization registry. Montana's imMTrax is a confidential, population based system used to collect, consolidate, and maintain vaccination data in one location, which is designed to make immunization requirement tracking and related activities easier because all of the data will be in one location. The immunization program is working toward a fully functional and complete registry but challenges remain.

These challenges, discussed in more detail in Chapter VI, include data completeness, data validation, and other issues. Further study in this area, such as an Information Systems Audit of the imMTrax system, could fully evaluate the extent of these challenges and make recommendations to assist the department in addressing them.

Report Contents

The remainder of the report provides additional background; presents audit findings and conclusions; and makes recommendations in the following areas:

- ♦ Chapter II provides program background.
- ♦ Chapter III considers Montana's required immunizations and preschool enforcement.
- ♦ Chapter IV examines the role of the department and of local health departments in enforcing the immunization of children in child care.
- ♦ Chapter V analyzes how children in school are protected against vaccine preventable diseases through enforcement by the department.
- ♦ Chapter VI considers the effective and efficient use of the department's immunization registry, imMTrax.

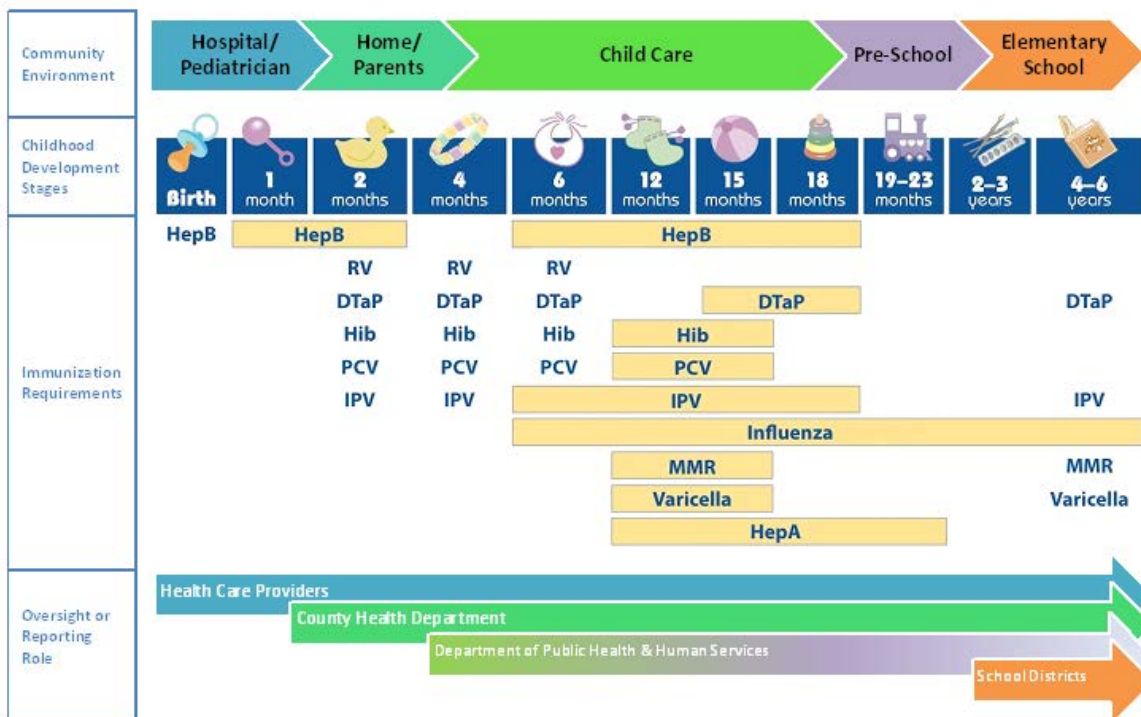
Chapter II – Background

Continuation of Immunization Coverage Protects Montana Children and General Public

State immunization programs depend on the Centers for Disease Control and Prevention's (CDC) setting of the childhood immunization recommendations via the medical experts on the Advisory Committee on Immunization Practices (ACIP). States then have varying approaches to adopting the recommendations. In Montana, there are lists of age-appropriate immunizations that generally all children must receive prior to attending a Montana child care, preschool, and school located in state law and rule. Child care immunization requirements are in the Administrative Rules of Montana (ARM) 37.95.140. Preschool requirements are also in rule, ARM 37.114.704. School requirements are in state law, §20-5-403, MCA.

These requirements are part of a continuation of immunization coverage designed to protect young children in child care, preschool, and school from vaccine preventable diseases. Figure 2 (on page 8) illustrates this continuation of coverage by showing the different environments in which children spend their time, immunization requirements from the ACIP, and the entities that have reporting or oversight roles regarding the immunization of Montana's young children. More information regarding specific immunizations are found in Appendix A.

Figure 2
Continuation of Immunization Coverage



Source: Compiled by the Legislative Audit Division from Centers for Disease Control and Prevention and department records.

This continuation protects the general public health as well because it reinforces existing herd immunity by reducing the number of nonvaccinated individuals in a community, thereby making the spread of disease more difficult.

Department of Public Health and Human Services Oversight Responsibilities

There are ramifications for noncompliance with these requirements. If documentation of a child's age-appropriate immunizations is not provided, the child is to be excluded, meaning they should not be allowed to attend the child care, preschool, or school until the requirements are met. If a pupil is excluded from school, the Department of Public Health and Human Services (department) or the local health department may seek an injunction requiring the parent, guardian, or responsible adult to present evidence to the school the pupil has been immunized, take action to fully immunize the pupil against the diseases, or file for an exemption. Any person not complying with these immunization requirements can be subject to an up to \$500 civil penalty. While the department is not responsible for exclusion of pupils, the department does have a role

in ensuring immunization requirements are met and the public is protected against vaccine preventable diseases.

The department works with local partners to make sure children have received the age-appropriate immunizations prior to attending a Montana child care or school. There are two processes in place designed to accomplish this.

The department contracts with local health departments to conduct site visits of child care facilities in their local jurisdictions to determine if all the attendees' immunization records are present and up-to-date. In Montana, one local health department is generally located in each county, although six counties in central Montana have joined together to create a combined health department, and there are several joint county and city health departments across the state. Local health department staff interact directly with members of the community through their clinics and provide feedback to the department on numerous topics. They submit quarterly reports to the immunization program regarding child care facilities they have assessed and the immunization status of the attendees. Similarly, the department depends on schools to report on the immunization status of their pupils. Schools submit reports to the immunization program once a year.

Unless an organization is attached to a child care, there is currently no monitoring of preschool attendees. This is discussed further in Chapter III.

Attendee Immunization Status Options

When reporting on the immunization status of a child, there are five general categories. "Excluded" means the child is not attending because they have not had the required immunizations. In contrast, "up-to-date," means the child has received all of the state-required immunizations for their age and institution. The three remaining categories, defined below, also allow the child to continue attending the institution.

- ♦ **Conditionally attending:** A child having at least the first shot of each series required for their age and institution, as well as a documented "catch-up plan," which will bring them up-to-date within a certain time, signed by a medical professional, is allowed to attend the institution. An example would include a child that has missed two doses in a series. It may not be medically advisable for that child to catch-up in a short time frame.
- ♦ **Medical exemption:** In some cases, it may not be medically advisable for a child to receive all the immunizations generally required for their age group. Documentation signed by a medical professional indicating the contraindication is required.
- ♦ **Religious exemption:** If the parents/guardians of a child attending school are religiously opposed to immunizations, they may submit their request

for an exemption annually. This exemption is not permitted for child care or preschool except for one immunization required of child care attendees, *Haemophilus influenzae* type b.

While the department depends on schools and local health departments to submit the information, the department has a role in ensuring the state's laws protecting children against vaccine preventable diseases are properly enforced.

Registry Designed to Make Immunization Tracking More Efficient

Montana's "imMTrax" is a confidential, population based system used to collect, consolidate, and maintain the vaccination data of Montanans in one location. The system is designed to make immunization requirement tracking and related activities more efficient and effective through centralized data storage and access.

A record for every child born in the state is created through a transfer of information from the state's electronic birth records system. Immunization data is then added to the child's record by health care providers. This can include general contact information like name, address and phone number; parent/guardian; and primary health care provider. Over time, as the child receives more immunizations, additional information is then added to the child's record such as immunization type and date received, contraindications for any vaccines, and other health information relevant to immunizations. New information can be added directly by a health care provider or through an electronic transfer of information.

The registry is currently used by some health care providers as a resource to check on the immunization status of patients. It is also used by some local health department staff to check the immunization status of children at the child care facilities they are assessing as part of their responsibilities in their contract with the department.

In Montana, individuals may choose not to have their, or their child's, immunization information included in imMTrax. The imMTrax system is discussed in more detail in Chapter VI.

Chapter III – Required Immunizations and Preschool Compliance

Introduction

The Department of Public Health and Human Services (department) requires potential attendees of facilities where numerous people are present to receive immunizations against certain diseases prior to attending.

This chapter addresses our first audit objective to determine if the department effectively enforces child care, preschool, and school compliance with existing immunization requirements. Our audit work showed that Montana's existing immunization requirements do not align with current Standards of Care related to immunizations for protection against vaccine preventable diseases. We also found limited monitoring and enforcement at preschools by the department. The remainder of this chapter discusses these findings.

Montana Immunization Requirements Less Than Experts Recommend

The annual childhood immunization schedule recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is put together by a group of medical and public health experts that have reviewed the available data on new and existing vaccines. This schedule is adopted by the American Academy of Pediatrics and the American Academy of Family Physicians. The Montana Vaccine for Children Program, a federally funded effort providing vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay, also lists ACIP recommendations as the standard practice for immunization coverage and generally requires providers to follow ACIP recommendations. Section 2-18-704(8)(b)(ii), MCA, specifically identifies the ACIP recommendations as the immunizations that must be covered in state employee insurance plans. Also, §33-30-1014 (2)(b), MCA, identifies ACIP recommendations as the immunizations that must be covered by disability insurance plans offered by health service corporations in the state.

In 2013, the schedule included immunizations against 14 harmful and potentially deadly diseases through a series of more than 30 different shots between birth and age 6.

Montana requirements in state law and rule do not currently include all of the ACIP recommended immunizations. They also do not include all of the immunizations

measured by the CDC in coverage rates for 19- to 35-month-olds. Table 1 illustrates these differences by comparing the ACIP immunization recommendations and immunization requirements for attendance at Montana child care, preschool and schools. Areas of concern are highlighted in blue.

Immunization	Included in ACIP Recommendation	Required for Attendance in Montana Licensed/Registered Child Care (ARM 37.95.140)	Required for Attendance in Montana Preschool (ARM 37.114.704)	Required for Attendance in Montana School (§20-5-403, MCA)
DTaP to protect against diphtheria, tetanus, and pertussis	Yes	Yes	Yes	*Yes
IPV to protect against polio	Yes	Yes	Yes	Yes
MMR to protect against measles, mumps, and rubella	Yes	Yes	Yes	Yes
Hib to protect against Hemophilus influenza type b	Yes	Yes	Yes	**No
Hepatitis B to protect against the disease	Yes	No	No	No
Varicella to protect against chicken pox	Yes	Yes	No	No
PCV to protect against pneumococcus	Yes	No	No	**No
Influenza to protect against the disease	Yes	No	No	No
Hepatitis A to protect against the disease	Yes	No	No	No
RV to protect against rotavirus	Yes	***No	***No	***No

Source: Compiled by the Legislative Audit Division from Centers for Disease Control and Prevention and department records.

* Section 20-5-403, MCA, does not require pertussis vaccination for children 7 years of age or older.
 ** Not recommended by the ACIP in children older than 5.
 *** Not recommended by the ACIP in children older than 8 months.

Other states more closely follow the ACIP recommendations and require immunizations against diseases Montana currently does not. For example, Montana is among only:

- ♦ 3 states not requiring varicella immunization for kindergarten entrance.
- ♦ 6 states not requiring Hepatitis B immunization for kindergarten entrance.
- ♦ 11 states not requiring Hepatitis B immunization for child care attendees.

- ♦ 17 states not requiring the PCV-Pneumococcal Conjugate immunization for child care attendees.

States have varying mechanisms for adopting ACIP recommendations and tailoring them for their immunization programs; some making it easier to more quickly respond to changes made by the ACIP. In Idaho, the Board of Health and Welfare adopts the rules for their immunization program, which includes new required immunizations. In Wisconsin, the Secretary of the Department of Health Services has the authority to add required vaccinations to that state's list of requirements.

In Montana the current process for updating required vaccinations involves changing a rule or law. Because the legislative environment is more geared to long term and comprehensive policy making, changing state laws related to required immunizations is generally not seen as an effective approach for reviewing the intricacies of new vaccines and their potential public health benefits. However, the department has not attempted to update the kindergarten vaccine requirements for many years.

The rules related to required immunizations have not been updated in more than four years, and some laws related to immunizations have not been updated in more than 30 years. Montana's immunization lists have the potential to become significantly out of date in relationship to the national recommendations, which in turn, are largely how rankings of immunization coverage are determined. Meaning a child could be up-to-date according to Montana rule and law but still bring Montana's immunization coverage rate down because they are not up-to-date according to the instrument the CDC uses to measure coverage.

More importantly, out-of-date immunization requirements increase the public health risk. The absence of CDC/ACIP recommendations on the state's required lists of immunizations prevents the department from having the authority to require those shots, and with every year that passes, Montana's children are at a greater risk of not receiving the immunizations experts have determined are necessary best practices to protect their own and the general public's health.

RECOMMENDATION #1

We recommend the Department of Public Health and Human Services:

- A. *Propose rule changes and seek legislation to align Montana's child care, preschool, and school immunization requirements with the Advisory Committee on Immunization Practices recommendations.*
 - B. *Establish a process to regularly determine if changes are needed to immunization requirements.*
-

Preschool Immunization Compliance

Montana law and rule define preschools, list the specific immunizations required for preschool attendance, require the immunization status of preschool attendees be reported to the department, and detail the processes for conditionally attending or obtaining a medical exemption for preschool attendees.

The department currently does not monitor immunization requirement compliance at Montana's preschools. An exception is when the preschool is run in combination with a licensed or registered child care, the compliance of the preschool attendees will be enforced in conjunction with the child care. The lack of monitoring of preschools is not only contrary to rule and statutory requirements but also creates a deficiency in Montana's continuation of immunization coverage, which is designed to protect children attending facilities where numerous people are present.

Other states have more complete continuation of immunization coverage. In Idaho, in addition to child care and school immunization enforcement, the immunization status of attendees in preschool is monitored. It is similar to how the state monitors their pupils in kindergarten through grade 12. Parents/guardians must provide documentation of current age appropriate immunization status to the preschool they wish their child to attend. If the documentation is not presented, or it is not up-to-date, the child will not be allowed to attend the preschool. Exceptions are allowed for medical or religious exemptions and children with conditional attendance plans.

Preschool Attendee Population Unknown

The department indicates its focus on child care immunization requirements in Montana developed largely because the immunization program offered to assist with the immunization aspect of the already existing efforts of the department's licensing bureau in regulating child care facilities. However, there is no such structure currently

for preschool regulation. They are neither licensed nor monitored. Consequently, the department is unable to determine how many preschools independent of child care facilities exist in the state, which hampers its ability to determine what kind of resources would be necessary to begin enforcing the immunization compliance of preschools. The department indicates preschool immunization is an area they should be looking at and states that the main task would be identifying the preschools, and then they could add preschools to its current child care assessment process.

The lack of data about preschools makes it impossible to directly report how many children are affected. More general numbers are available, and can help us understand the magnitude of the issue. According to the U.S. Census Bureau in 2012, there were approximately 61,000 children under age 5 in the state. The 2012 Kids Count report indicates there were about 20,000 licensed and registered child care slots, indicating that 41,000 or about two-thirds of Montana children under age 5 were in an environment that had no immunization requirement protections. Interpolation of this data with 2012 kids count report data regarding preschool and kindergarten enrollment estimates a preschool population in the state of 4,300-7,600.

State law provides that the governing authority of any school, including preschools, has enforcement authority to prohibit attendance of pupils who have failed to obtain required immunizations. It also provides the department the authority to track and enforce school, including preschool, compliance with immunization requirements. The local and state health departments are to have access to all information relating to immunization of any pupil in any school. If a pupil is excluded from school, the department or the local health department may seek an injunction requiring the parent, guardian, or responsible adult to present evidence to the school that the pupil has been immunized, take action to fully immunize the pupil against the diseases, or file for an exemption.

While the department is not responsible for exclusion of pupils, it is the department's responsibility to make sure the children attending preschools are protected against vaccine preventable diseases. Children without immunizations are a potential health threat to their classmates, younger siblings, others who have not been immunized, and the general public.

The department has a variety of steps it can take to begin the process of monitoring preschools, including:

- ◆ Gathering data regarding preschools from local health departments.
- ◆ Collecting information about preschools from schools.
- ◆ Researching business licenses with "preschool" in the business name.

RECOMMENDATION #2

We recommend the Department of Public Health and Human Services develop and implement a documented process to ensure preschool attendee compliance with immunization requirements.

Chapter IV – Protecting Child Care Attendees

Introduction

Child care facilities are among those entities at which Montana law and rule require attendees be vaccinated against certain diseases. This chapter addresses our first audit objective to determine if the Department of Public Health and Human Services (department) effectively enforces child care facility compliance with existing immunization requirements. Audit work found that controls to ensure consistency related to child care assessments could be improved, as could controls designed to ensure follow up with children being reported as either noncompliant or conditionally attending. In addition, controls regarding the selection of child care facilities for annual assessment do not currently ensure all facilities are assessed on a regular basis. The remainder of this chapter discusses these findings.

Child Care Attendees Must Meet Immunization Requirements

Table 2 provides information by age group on Montana's population from birth to age 5 and the facilities they might attend which have immunization requirements.

Table 2 <u>Population of Montana Children Birth to Age 5 and Facilities Their Age Group Might Attend</u> 2012			
Age	Number	Potential Facilities with Immunization Requirements	Continuation of Immunization Coverage
Under 3 years	35,807	Child Care	Approximately 60,862 children under age 5 and 20,000 Licensed or Registered Day Care Slots with immunization requirements. Preschool estimate 4,300-7,600.
3 and 4 years	25,055	Child Care Preschool	
5 years	12,889	Elementary School	Immunization requirements are mandatory to start kindergarten, which generally begins when the child is age 5.

Source: Legislative Audit Division interpolation from U.S. Census, Kids Count Report, and department records.

The department is required by state law to adopt rules for the protection of children in child care from various health hazards, including communicable diseases. Administrative rules require children receive certain age appropriate immunizations prior to attending child care. This rule also requires a child be immediately excluded from attendance at a child care if they are not vaccinated and do not have a record of medical exemption or conditional enrollment. A religious exemption is available for one immunization required of child care attendees, *Haemophilus influenzae* type b, but not for others. Responsibility regarding exclusions varies within the department depending on the size of the child care. Based on department policy, the exclusion of a child from a smaller (12 or fewer attendees) family or group child care facility is the responsibility of the licensing bureau of the Quality Assurance Division, while exclusions at larger (13 or more attendees) child care centers is the responsibility of the local health departments based on a contract they have with the immunization program.

As discussed in Chapter II, the department contracts with local health departments to conduct site visits of child care facilities in their local jurisdictions to determine if all the attendees' immunization records are present and up-to-date. The exact expectations of the local health departments related to these tasks are documented in what most refer to as an Immunization Action Plan (IAP) contract between the immunization program and the local health departments.

Among the expectations of the IAP contract are quarterly reports containing data related to the attendees of the child care facilities that were assessed. These reports include spaces for local health department staff to indicate the number of children that do not have up-to-date immunization records, meaning they are noncompliant with the requirements; have no immunization records, which is also noncompliant; or are conditionally attending, which means the child does not have all of the required immunizations but is on an established plan to receive them in a certain time frame and in the meantime can attend the child care.

Child Care Assessment Inconsistencies

Our survey of local health department staff regarding IAP contract related activities identified inconsistencies among local health departments regarding how IAP contracts are implemented. Examples include inconsistencies regarding whether respondents felt they had the authority to exclude children from a child care for noncompliance. Other inconsistencies identified through survey work include:

- ♦ Inconsistencies in the process and length of time provided to a child care center to have an individual child come into compliance with immunization requirements. Department policy states the center has 14 days after being

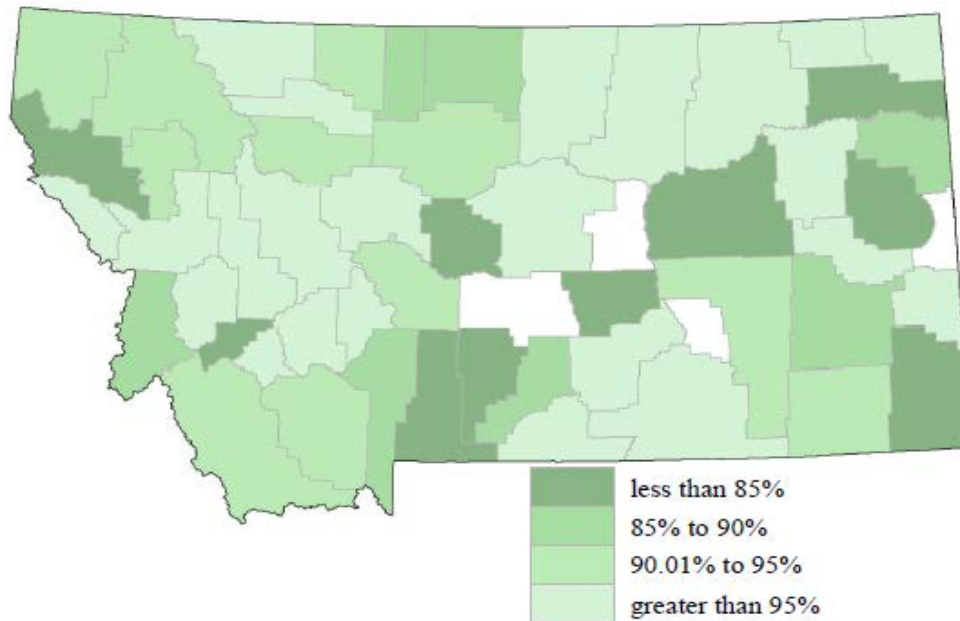
notified of the noncompliance. Many responses included contacting the parents or child care center weekly to see if the paperwork has been received at the center. However, others were unspecified such as “each situation is managed on a case-by-case basis.”

- ◆ Inconsistencies in the process local health departments report using for interacting with a child care that is not in compliance with immunization requirements, such as no immunization files, or files indicating incomplete immunizations for the child’s age. Of the 36 local health department staff who answered the question related to their process for interacting with a child care in noncompliance, 5 responded that this is generally not a problem, 4 stated they would let the state know of the noncompliance, and 4 mentioned conditional attendance forms being put in place while compliance is achieved. There appears to be an emphasis on education rather than exclusion of the children not in compliance, which is required after 14 days.

A review of IAP quarterly reports indicates the possibility of varying levels of protection against vaccine preventable diseases provided to child care attendees and the general public. One local jurisdiction may be very strict, while the next lax.

A review of IAP quarterly reports from a sample of five counties indicate there are child care reports which include children listed as not in compliance with the immunization requirements rule and some which do not. Because there is no documented follow-up for children not in compliance, it is not possible for the department to determine if this is because a local health department made sure all attendees at the child care facilities they assess are in compliance before reporting, or whether all were children compliant for the sample period. Figure 3 (on page 20) shows the child care immunization compliance rates of Montana counties in 2012.

Figure 3
Child Care Immunization Rate by County
 2012



Data not available for counties in white

Source: Compiled by the Legislative Audit Division from department records.

Follow-up Needed for Child Care Attendees not in Compliance With Immunization Requirements

In 2012, department records indicate of the 15,320 children whose records were assessed, 1,397 children (9.1 percent) were identified as either not having up-to-date records, having no immunization record, or conditionally attending. The department indicates that while it depends on the local health departments to follow up on these children, there is no requirement in the IAP contracts that they do so or that they document how or whether these children come into compliance with the immunization requirements.

Additionally, the department is unable to know if exclusions are occurring as they should because there is no documented, systematic follow up with local health departments regarding attendees that are reported as noncompliant. Children may be attending child care without the required immunizations, putting other attendees as well as the general public at risk for vaccine-preventable diseases.

RECOMMENDATION #3

We recommend the Department of Public Health and Human Services:

- A. *Expand contract provisions with the local health departments to follow up on children reported as noncompliant or conditionally attending.*
 - B. *Follow up with local health departments to ensure exclusions occur in compliance with immunization requirements.*
-

Child Care Assessment Selection Process Could Be Improved

The IAP contract requires local health departments to annually assess 80 percent of the licensed child care centers (13 or more attendees) in their jurisdiction. For example in 2012 in Yellowstone County, there were 36 child care centers identified; the local health department was required to assess 80 percent of the centers or 29. The local health department currently may select any 29 of the 36 centers to assess to meet this threshold.

Local health departments with 10 or fewer licensed centers in their jurisdiction, must assess all of the centers, as well as 80 percent of family and group child care (12 or fewer attendees) facilities. For example in 2012 in Lincoln County, there was 1 child care center identified as well as 11 family and group child care facilities. The local health department was required to assess the 1 center as well as 9 (80 percent) of the family and group facilities. Again, the local health department currently may select any 9 of the 11 centers to meet this requirement.

Consequently, a local health department could consistently select the same child care facilities to assess every year, meaning another group of child care facilities in their jurisdiction would not be routinely assessed. This creates a situation where children could be attending a child care facility that has never been assessed for immunization compliance by the Immunization Program.

In addition, the requirement is related to the number of child care facilities, not the number of children. Especially in those counties with many larger child care centers, the possibility of the local health department consistently choosing child care facilities with smaller enrollment numbers to assess creates a situation where large numbers of children could be attending a child care center that has never been assessed for immunization compliance by the Immunization Program.

We identified specific child care facilities that according to Immunization Program records appeared not to have been assessed by the local health department in two consecutive years. The IAP contract language regarding this topic was developed as a way for the department to establish an assessment threshold but not require 100 percent of the child care facilities be assessed annually. The department feels 100 percent would not be realistic compared to the small amount of funding the program is able to provide to the local health departments.

While we understand the department's position on requiring 100 percent of child care facilities be reviewed, we believe the department could better ensure child care facilities are consistently reviewed. For example, the department could keep its current 80 percent requirement and add a requirement that each facility be reviewed within an established time frame.

RECOMMENDATION #4

We recommend the Department of Public Health and Human Services strengthen its annual child care assessment selection process to ensure all facilities are consistently assessed.

Chapter V – Protecting Elementary School Attendees

Introduction

Montana's continuation of immunization coverage is designed to protect children and the general public against vaccine preventable illnesses by ensuring attendees at various facilities, including schools, are in compliance with immunization requirements. State law and rule require kindergartners be vaccinated against certain diseases prior to entering elementary school.

This chapter addresses part of our first audit objective regarding whether the Department of Public Health and Human Services (department) effectively enforces school compliance with existing immunization requirements. Audit work found that improvements could be made to better ensure elementary school immunization compliance. The remainder of this chapter discusses these findings.

Department Collects Data Regarding School Compliance With Immunization Requirements

According to Montana's Office of Public Instruction (OPI), during the 2012-2013 school year, there were 11,708 kindergartners in Montana. Enrollment in first through sixth grade was 66,256. Since elementary school students routinely come into contact with pupils in grades other than their own, including kindergartners, nearly 78,000 children are directly affected by kindergarten entry immunization requirements. The importance of herd immunity is heightened because school attendance is generally mandatory.

Section 20-5-403, MCA, states the governing authority of a school may not allow a person to attend as a pupil unless the pupil has been immunized against various diseases, qualifies for conditional attendance, or files for an exemption. In addition, state law and rules require schools to:

- ♦ File a report on the immunization status of all pupils under its jurisdiction with the department and the local health department.
- ♦ Have all information relating to immunization of any pupil in any school available for access by the department and the local health department.

If a pupil is excluded from school, the department or the local health department may seek an injunction requiring the parent, guardian, or responsible adult to present evidence to the school that the pupil has been immunized, take action to fully immunize the pupil against the diseases, or file for an exemption.

While the department is not responsible for exclusion of pupils, the department does have a role in ensuring immunization requirements are met and the public is protected against vaccine preventable diseases. Additionally, as established in ARM 37.114.720, the department is responsible for collecting the Annual School Immunization Survey data used by the Centers for Disease Control and Prevention (CDC) to assess vaccination coverage for communities and identifying groups of children that may lack connections to the primary care system. The CDC requires information about kindergarten and 7th grade students; the Montana program collects information regarding pupils in all grades K-12.

The Department Conducts the Annual School Immunization Survey

Schools currently submit information to the department regarding the immunization status of their pupils via a web based reporting site. This information includes the number of students per grade at the school, those pupils without immunization records, those with exemptions, and those conditionally attending. They also collect information regarding each required shot. The audit focused on the requirements for kindergarten entrance. The department's goal is to get the information from all schools, including public, private, and nonaccredited schools. The department currently begins this process by obtaining a list of all accredited public schools from OPI. This list usually includes more than 850 schools. The department then adds private and nonaccredited schools to the list based on information it has received from these schools during previous year's submissions.

The department contacts the schools on its list early in the school year to remind them of the required reports. If the schools have not reported by the December 1st deadline, the department sends two more reminders in order to get a response from the nonreporting schools. After collecting the data each year from schools, the department reports this data to the CDC. In addition, the department compiles aggregate and regional data and provides the data to all the schools and local health departments.

Audit Work Identified Inconsistencies in Annual School Immunization Survey

As part of our audit work, we reviewed the data compiled by the department based on school reports for 2010 through 2012 and identified:

- ♦ The department does not independently verify the accuracy of the data submitted by the school.
- ♦ Inconsistencies occurred in the names of schools from year to year.
- ♦ Inconsistencies occurred in which schools reported from year to year. For example, one school reported data in 2010 and 2012, but not in 2011.

- ♦ For the schools that did not report, based on department records, we could not identify the number of pupils enrolled in the school.

The school reporting form includes spaces for recording the number of children with no immunization records, conditionally attending, or exemptions. Table 3 illustrates the number of kindergarten students in each of these categories reported during the 2012-2013 school year.

Table 3 <u>Kindergartners Reported in Various Immunization Status Categories</u> 2012-2013 School Year			
No Immunization Record	Conditionally Attending	Medical Exemption	Religious Exemption
1	14	67	235

Source: Compiled by the Legislative Audit Division from department records.

However, with no data from nonreporting schools, it is not possible to determine the immunization rate for Montana kindergartners as a whole and whether additional students would be assigned these categories.

Formalized Policy and Procedures Regarding School Data Are Needed

While the department has implemented a new electronic reporting system for schools to more effectively report immunization data, we did not identify formalized policy and procedures regarding how department staff should collect, compile, and report school data.

While the department reports the immunization survey response rate of schools turning in information regarding their pupils in the 2012-2013 school year was approximately 96 percent, based on our audit work, it is difficult to ascertain what the 96 percent reflects. The exact list of schools, which would serve as denominator in any percentage calculation, is not readily identifiable from program records. Additionally, the department does not have a process in place to further analyze school report data to determine the validity of the school's reported numbers.

Diminished management information makes data-based decision-making difficult, and resources cannot be effectively directed based on need. Additionally, if the department is not aware of pupils without up-to-date immunization records, the

department is unable to determine whether exclusions are occurring as they should. Meaning, children may be in school without the required immunizations, putting other attendees as well as the general public, at risk for vaccine preventable diseases.

According to the CDC, school entry surveys should reflect an accurate picture of immunization levels of children entering school. In other states we contacted, schools also self-report immunization information but some have a process to independently verify the information. For example, North Dakota tests a sample of data received in their school reports against the data in the state's immunization registry. While the department may be able to validate records for some pupils using Montana's registry, other tools such as OPI's enrollment numbers are also available.

When discussing these concerns with department staff, the department stated it depends on the schools or the local health departments to follow up on children not reported or reported as having no immunization record. While the department depends on schools to submit the information, it is the department's responsibility to ensure the state's laws protecting children against vaccine preventable diseases are properly enforced.

RECOMMENDATION #5

We recommend the Department of Public Health and Human Services:

- A. *Develop formalized policy and procedures regarding the compilation and verification of school reports.*
 - B. *Develop a documented process to actively monitor school attendee compliance with immunization requirements.*
-

Department Should Monitor Pupils' Conditional Enrollment Requirements

Montana Administrative Rule 37.114.721 requires schools to notify the department and the local health department if a student has been excluded for failing to meet the requirements of conditional enrollment. This means if a student does not receive the required immunizations in the time frame agreed to when they were allowed to continue attending school, the school is to exclude them and notify the department and the local health department. The report must include the child's name, address, parent or responsible adult, and the day of the exclusion.

Through our audit work, we found the department has not developed policy or procedures to follow up with students who are conditionally attending, or track excluded students. Additionally, the department has not communicated this notification requirement to schools.

In interviews with local school officials responsible for reporting immunization information to the department, we found that, while rare, school exclusions for immunization noncompliance have occurred. The department does not currently track this information, so it has no record of exclusions, and there is also no way to determine how many of the exclusions are the result of failing to meet the requirements of conditional enrollment.

Since the department is unaware of whether schools have excluded and/or should be excluding pupils who do not meet conditional enrollment requirements, children may be in school without the required immunizations, putting other attendees, as well as the general public, at risk for vaccine preventable diseases.

RECOMMENDATION #6

We recommend the Department of Public Health and Human Services develop a documented process to:

- A. *Notify schools about the requirements of ARM 37.114.721.*
 - B. *Track students excluded for failing to meet the requirements of a conditional enrollment.*
-

Chapter VI – Montana’s Immunization Registry, “imMTrax”

Introduction

The Centers for Disease Control and Prevention (CDC) indicate that a significant barrier to achieving a more fully immunized population is the lack of dependable and centralized immunization records. Consequently Montana, and all other states, are working toward achieving a complete and fully functional immunization registry for their states’ populations. Immunization registries are designed to make immunization requirement tracking and related activities more efficient and effective through centralized data storage and access. The annual costs of the registry in Montana is approximately \$200,000 in federal funds.

This chapter addresses our second audit objective to determine if the Department of Public Health and Humans Services (department) has controls in place to ensure efficient and effective use of Montana’s Immunization Registry (imMTrax) in order to protect public health and safety. Our audit work identified several issues affecting use of the system, including a lack of statutory guidance regarding the sharing of information within imMTrax, and the need for improved controls to ensure data within the system is accurate and reliable. The remainder of this chapter discusses these findings.

How the Immunization Registry Works

In Montana’s registry, imMTrax, a record for every child born in the state is created through a transfer of information from the state’s Vital Statistics Information management system. Immunization data is then added to the child’s record by health care providers. This can include general contact information like name, address and phone number; parent or guardian; and primary health care provider. Over time as the child receives more immunizations, additional information is then added to the child’s record such as immunization type and date received, contraindications for any vaccines and other health information relevant to immunizations. This kind of information is covered by Health Insurance Portability and Accountability Act (HIPAA) privacy protections.

A child born in Montana generally receives their first dose of the Hepatitis B vaccine before leaving the hospital when they are born. The immunization registry system is set up so that after the birth record is filed, information such as name, date of birth, sex, and data regarding their first dose of the Hepatitis B vaccine is transferred to imMTrax. The child is then recommended to have another Hepatitis B dose within their first two months of life. This immunization might occur at their one month

checkup with their pediatrician. The registry is designed so the pediatrician should be able to pull up the child's record in imMTrax and see the date the child received their first dose of Hepatitis B and if there were any complications. The pediatrician can then record the second dose of Hepatitis B for the child. For the child's two month checkup, there are four recommended vaccines. If the child sees a doctor other than their usual pediatrician for this checkup, imMTrax is designed to allow the other doctor to pull up the child's record and determine which shots they have received and which ones are due. The registry is intended to record all of the information related to this child and all of the vaccines received regardless of where in the state they receive the immunizations.

Public Health Benefits of Sharing Immunization Data

In 2013 the recommended schedule of immunizations included a series of more than 30 different shots between birth and age 6 to protect against 14 diseases. The registry can help health care providers navigate this complicated matrix and determine when a patient is due for a vaccine and also prevent too many vaccines from being administered to a child. It is used by some local health department staff to check the immunization status of children at the child care facilities they are assessing. In addition to these health care benefits, in our increasingly mobile society, this single location for immunization data can be beneficial for parents needing to present documentation of their children's immunization for entrance to kindergarten or child care. Also, local health department staff can use the registry to determine the risk of their county's population if an outbreak of a vaccine preventable disease occurs. Using the registry, they are able to see how many people in their county are not vaccinated against that particular disease, and plan accordingly.

Statutory Guidance for Immunization Registry Use

The efficient and effective use of immunization registries depends on a number of factors. For example, the CDC indicates that data in a successful registry should be complete. So it is essential that as many children as possible be included in the registry and as many of their immunizations as possible be recorded. States utilize various approaches to increase the completeness of their registry data. For example in North Dakota and Arizona, state law requires health care providers to enter immunization data into their registry; it is voluntary in Montana. In Oregon state law provides guidance on definitions of authorized users of their registry and gives an example of a "potential catastrophic disease threat" which allows emergency use of data in the registry by some users.

Another example of statutory guidance that is given in other states relates to individual participation in the registry. There are two models states can choose for individual

participation in a state immunization registry like imMTrax. The first is “opt-out.” This means any person who does not want to have their immunization information included in the registry must request to “opt-out” of it. Contrasted to an “opt-in” state, meaning before any individual’s immunization information is submitted to the registry, the health care provider must secure the person’s signature to “opt-in.” There are 44 states with opt-out systems, and six including Montana with opt-in systems.

Opt-In Requirements Affect Data Completeness

Our survey of local health department staff regarding their use of the registry indicated that of the 27 individuals responding to a question regarding what affects their use of the registry, 14, or 52 percent, said opt-in requirements. Local health department staff can be affected by opt-in requirements in two ways. Survey respondents noted that opt-in requirements reduce the usefulness of the registry when they are unable to check on the immunization status of one of their new patients, or a child in a child care they are assessing, because a previous health care provider had not gotten consent from the child’s parents to include the information in the registry.

The second way opt-in requirements affect local health departments is the extra time that is required to secure consent. The concern is that because of time constraints, a health care provider may not give a parent that opportunity, which keeps useful information that otherwise would have been included out of the registry. While many choose to include their child’s information in the registry, there are some that do not. In opt-out systems, there remains an avenue for this to occur.

Department management also indicated that opt-in requirements reduce the efficient and effective use of the registry. The lack of information that otherwise would be included in imMTrax, except for time constraints on a health care provider, presents public health concerns because data in the registry is not complete. Our survey of local health department staff regarding their use of the registry indicated of 36 individuals responding to a question regarding whether using imMTrax increases their organization’s immunization coverage rate, 28 (77 percent) said yes. Local health department staff indicated that the registry allows them to more efficiently assess a child’s immunization status because all of the data is one place. However, this capacity is diminished because the data is not complete because information is being kept out of the registry because of opt-in requirements.

The department currently operates the imMTrax system under its broad statutory authority to protect and promote public health, which includes preventing the spread of communicable diseases. However, there is no specific statutory guidance regarding use of the registry or information sharing between health care professionals and other

system users. The type of guidance that could be addressed in state law would include the following:

- ◆ Identification or definition of required or optional system users.
- ◆ Circumstances where opt-in or opt-out requirements should apply.
- ◆ Control over personal health information and access to records.
- ◆ Information sharing between the department and other public health entities.
- ◆ Departmental reporting responsibilities.

During the 2013 Legislative Session, legislation was introduced to change Montana to an opt-out state related to imMTrax, but the bill did not advance past an initial committee hearing. Given the lack of statutory directive on the issues discussed above, the department's ability to efficiently and effectively implement and maintain imMTrax has been affected. As a result, it is unclear whether the full public health benefits of the registry are being realized or whether the state's initial and ongoing monetary investment of \$200,000 annually in federal money is cost-effective. The CDC has encouraged the development of registries and some aspects of the VFC program requires the use of a registry; the use of registries is likely to increase due to the current view of the CDC. Seeking legislation to provide guidance on use of the immunization registry would allow the department to begin addressing data completeness and other issues.

RECOMMENDATION #7

We recommend the Department of Public Health and Human Services seek legislation providing guidance on the use of the state's immunization registry.

Data Quality Controls Could Be Improved

To test imMTrax controls we first reviewed the data input processes and quality control measures applied to those processes. These specific controls play a fundamental role in the quality of data in the system. The quality of the data, in turn, plays a fundamental role in the ability of the registry to be effectively and efficiently used.

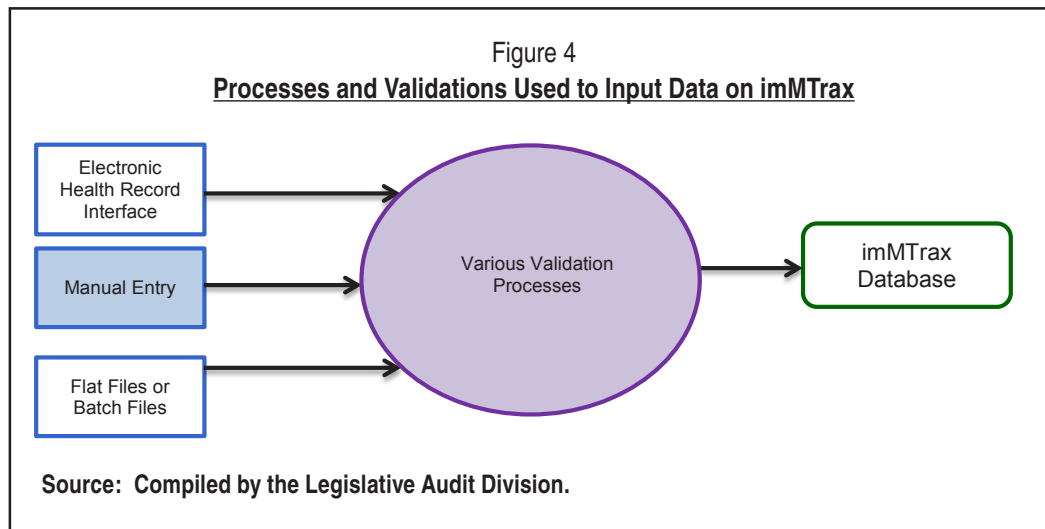
Our audit work found the quality of the data in imMTrax was a concern that affected the efficient and effective use of imMTrax by health care providers and others. Issues include multiple records of a single child, immunizations indicated as "not valid," when it appears they are valid, and submitted data not appearing in the system in a timely manner. In addition, common reports produced from immunization registry

data include “recall,” which are generated to identify patients who are behind on immunizations; “reminder,” which identifies those who will be due for immunizations soon; “vaccine usage,” which lists patients, immunizations given, etc., for a particular time frame, and “invalid shots,” which list patients who have received invalid immunizations due to interval constraints or age inappropriateness.

There is little usefulness in reports like these to protect public health and safety if they are based on unreliable, incomplete, or voluntary data; it reduces the likelihood of effective and efficient use of the registry. Data quality concerns raise public health issues too. Any child that does not have up-to-date immunizations poses a potential public health risk, especially to their younger siblings and others who have not been immunized.

System Documentation Could Be More Complete

Figure 4 (on page 34) illustrates how data flows into Montana’s immunization registry. There are currently three ways data is put into the registry: transfer of data through interfaces, manual entry, and upload of flat files or batch files through scripts. Manual entry occurs at the provider level where immunizations are given. Data regarding the child’s name, types of immunizations received, dates immunizations received, etc. is directly entered into the imMTrax system by staff at the practice, clinic, or hospital. In contrast, the transfer of data through interfaces occurs when a health care provider has electronic health records which are set up to “talk” directly to the imMTrax system and eliminates the need for health providers to enter information regarding immunizations into both their electronic record system and imMTrax. The third process occurs when a provider has data that, rather than directly “interfacing” with the imMTrax system, sends a batch or flat file to the department. Script language is then run on the files to upload the data so it can be incorporated into the imMTrax system. There are processes that validate the data before entering the imMTrax system.



The processes for which documentation regarding data validation exists are indicated in blue (manual entry) and those that do not are in purple (various validations). The department does not have mappings of these processes including data flow between the systems. Additionally, the department does not have complete documentation regarding the validations applied to data for each software application.

Best practices recommend the documentation of information systems because it helps organizational personnel understand the implementation and operation of security controls associated with information systems. Specific guidance related to system documentation controls indicates that information system documentation should describe secure configuration, installation, and operation of the system; effective use and maintenance of security functions and mechanisms; and known vulnerabilities regarding configuration and use of administrative and privileged functions.

Best practices observe the inability to obtain needed documentation may occur due to the age of the information system or lack of support from developers and contractors. Our audit work found instances of both of these in relation to imMTrax. The staff working directly with this system have been with the program for less than 18 months. Their understandable lack of institutional knowledge compounds the issue of no system documentation regarding data validations. The staff working on the system have gathered some understanding from user manuals and what has been informally passed on to them, but little has been formally documented. Additionally, we found the contractor responsible for some of the data validations does not have readily accessible documentation regarding how validations are applied in specific applications.

While best practices indicate documentation should be recreated if it is essential to the effective operation of controls, the department is unable to understand the validation

points of data due to no formal documentation of data flow. Therefore neither department staff, nor we, could determine what controls were applied to immunization data prior to the data being put into imMTrax. This lack of documentation created an inability to test the validation points and therefore we could not obtain assurance over the data quality of the system.

RECOMMENDATION #8

We recommend the Department of Public Health and Human Services:

- A. *Develop written procedures and mappings for data flow into the immunization registry.*
 - B. *Determine what validations are applied to the data and document the findings.*
-

Privileged User Roles Should Be Restricted

One way the quality of data in an information system can be protected is by restricting access based on roles. Roles are created for various job functions and varying levels of access to the system are granted based on the business need of those roles. Specifically, best practices indicate the following controls related to role assignment.

- ♦ The organization should employ the principle of least privilege, allowing only authorized access for users which are necessary to accomplish assigned tasks in accordance with organizational missions and business functions.
- ♦ The organization should restrict privileged accounts on the information system to organization defined personnel or roles.
- ♦ The organization should require users of information system roles, with access to security functions or security relevant information, use nonprivileged accounts or roles when accessing nonsecurity functions.

During our audit, we found that 34 users of imMTrax were assigned “administrative user” status. These specific individuals can make changes to the data including adding data to tables, assigning roles to other users, and deleting previously recorded vaccines. Based on our review, 17 of these individuals were contractor users, 12 were department staff, and five more related to the department for specific functions. While this level of access was assigned to department and contractor personnel to allow them to perform certain aspects of their job, not all department staff require this kind of elevated access. This situation results in multiple users with the ability to create new users without proper approvals and both department and contracted staff with the ability to access, enter, and update data. Additionally, according to best practices, contracted staff should not have access to the production environment.

While the department recognizes the importance of restricting access, management indicated it utilized the roles that were already in the system. However, management also indicated those roles can be customized. Since unrestricted access can affect data integrity, we believe the department should strengthen its controls over its application roles to ensure only authorized individuals can accomplish higher level tasks.

RECOMMENDATION #9

We recommend the Department of Public Health and Human Services:

- A. *Create application roles that limit permissions assigned to only those required for the specific position.*
 - B. *Limit contractor access to production data.*
-

Privileged User Activity Should Be Monitored

Another way the quality of data in a computer system can be protected is by monitoring its use by those with privileged roles. Specifically, best practices indicate the following controls related to system monitoring:

- ♦ The computer system should audit the execution of privileged functions, and the organization should review and analyze those system audit records.
- ♦ The organization should monitor the use of information system accounts, and the monitoring should include looking for, and reporting, accounts with atypical use.
- ♦ The organization should develop a continuous monitoring strategy and implement a continuous monitoring program.

The system has the capacity to track user activity, but there is currently no review of the information. As discussed above, there are 34 users with administrative rights that use these roles in everyday operations. Misuse of these capabilities within the system could easily go unnoticed if review of user activity is not done. Currently users with the ability to manipulate data and system settings could change information in the immunization registry without management and/or other department staff knowing.

Additionally, some imMTrax users, such as lead public health nurses, are allowed access to personal health information in emergency situations such as during a disease outbreak. However, they are currently using this high level of access on an on-going basis. Potentially, users could inappropriately use their access to change and/or modify immunization registry data. While the department indicated the access was set-up this way initially to allow for quick use in emergency situations and they have concerns

regarding requiring two log-ins for these individuals, they are considering a plan to consistently monitor the use of those accounts. Given the sensitive nature of the information in the registry, it is particularly important that those with high level access to it should be monitored.

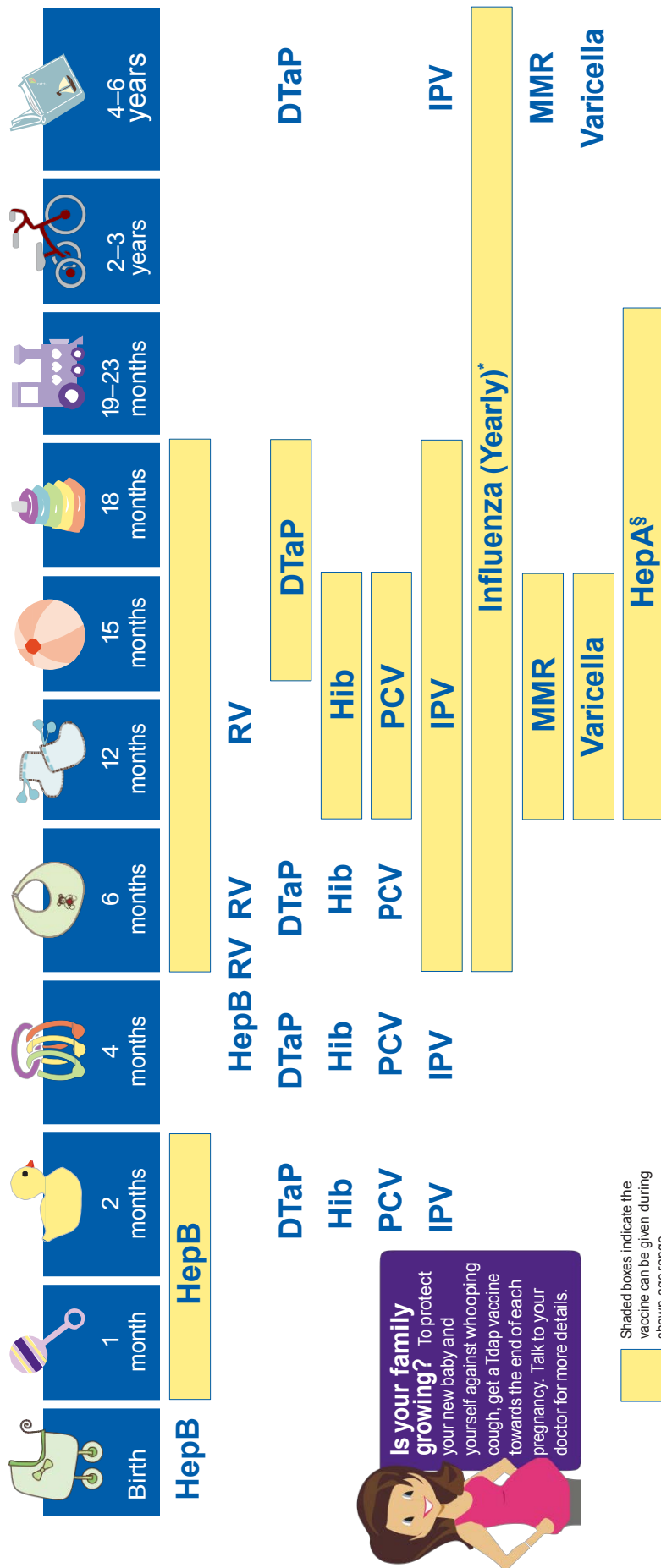
RECOMMENDATION #10

We recommend the Department of Public Health and Human Services develop and implement documented procedures for monitoring activity of users with privileged roles.

Appendix A

Appendix A appears on the next two pages and includes details on the Advisory Committee on Immunization Practices (ACIP) recommendations to protect children against 14 vaccine preventable diseases. It is published annually on the Centers for Disease Control and Prevention's (CDC's) web site.

2013 Recommended Immunizations for Children from Birth Through 6 Years Old



NOTE: If your child misses a shot, you don't need to start over; just go back to your child's doctor for the next shot. Talk with your child's doctor if you have questions about vaccines.

FOOTNOTES: * Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time and for some other children in this age group.

§ Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 to 18 months later. HepA vaccination may be given to any child 12 months and older to protect against HepA. Children and adolescents who did not receive the HepA vaccine and are at high-risk, should be vaccinated against HepA.

If your child has any medical conditions that put him at risk for infection or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.

See back page for more information on vaccine-preventable diseases that vaccines that prevent them.

For more information, call toll free
1-800-CDC-INFO (1-800-232-4636)
or visit
<http://www.cdc.gov/vaccines>



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

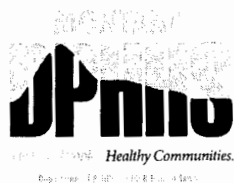
Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	Varicella vaccine protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	DTaP* vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	Hib vaccine protects against <i>Haemophilus influenzae</i> type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), intellectual disability, epiglottitis (life-threatening infection that can block the windpipe and lead to serious breathing problems), pneumonia (infection in the lungs), death
Hepatitis A	HepA vaccine protects against hepatitis A.	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure, arthralgia (joint pain), kidney, pancreatic, and blood disorders
Hepatitis B	HepB vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Flu	Flu vaccine protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	MMR** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pinkeye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	MMR** vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord), encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	DTaP* vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	IPV vaccine protects against polio.	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	PCV vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	RV vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	MMR** vaccine protects against rubella.	Air, direct contact	Children infected with rubella virus sometimes have a rash, fever, swollen lymph nodes	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, birth defects
Tetanus	DTaP* vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP combines protection against diphtheria, tetanus, and pertussis.

** MMR combines protection against measles, mumps, and rubella.

DEPARTMENT OF PUBLIC
HEALTH AND HUMAN
SERVICES

DEPARTMENT RESPONSE



Department of Public Health and Human Services

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MAY 02 2014

LEGISLATIVE AUDIT DIV.

Steve Bullock, Governor

Richard H. Opper,
Director

May 2, 2014

Sarah A. Carlson
Legislative Auditor
Office of the Legislative Auditor
State Capitol, Room 160
Helena MT 59620-1705

Re: Childhood Immunization Requirements in Montana

Dear Ms. Carlson:

The Department of Public Health and Human Services has reviewed the Childhood Immunization Requirements in Montana audit (13P-07) completed by the Legislative Audit Division. Our responses and corrective action plans for each recommendation are provided below.

Recommendation #1a: We recommend the Department of Public Health and Human Services: Propose rule changes and seek legislation to align Montana's child care, preschool, and school immunization requirements with the Advisory Committee on Immunization Practices Recommendations.

Response: Concur

Corrective Action: The department is in the process of drafting updated immunization rules for child care facilities. The revised rules will more closely align with recommendations of the Advisory Committee on Immunization Practices (ACIP) and add Hepatitis B and pneumococcal vaccine as required immunizations. While the addition of other recommended vaccines was considered, the decision was made to limit the additions to the vaccines most commonly required in other states.

In addition, the department is currently reviewing legislative proposals in preparation for the 2015 session. Proposals under consideration include updating school immunization requirements in statute or proposing rulemaking authority be given to the department to simplify updating as national recommendations change. Specifically, adding requirements for the varicella series and a pertussis booster for school-aged children is anticipated.

Planned Completion Date: We anticipate the revised rules will be in place by fall of 2014. Potential statute changes may be considered during the 2015 legislative session.

Recommendation #1b: We recommend the Department of Public Health and Human Services: Establish a process to regularly determine if changes are needed to immunization requirements.

Response: Concur

Corrective Action: None required. Review of department administrative rules occurs at least every other year in accordance with the Montana Administrative Procedures Act, 2-4-314 MCA.

In the specific case of rules related to immunizations, ARMs have received frequent review as the agency has been improving processes at the state and local level, responding to, or proposing, legislation and determining the most effective means of promoting vaccination efforts. The results of our efforts are reflected in our response to recommendation #1a outlining recent efforts in this area.

Planned Completion Date: Already in place

Recommendation #2: We recommend the Department of Public Health and Human Services develop and implement a documented process to ensure preschool attendee compliance with immunization requirements.

Response: Concur

Corrective Action: The department will continue our efforts to identify preschools and monitor compliance with immunization requirements outlined in statute and rule. As indicated during the audit review, no list of preschools is maintained by the Office of Public Instruction (OPI) or other state agency making this effort difficult. However, many sites identifying themselves as preschools are licensed or registered child care facilities and are reviewed by the department. At the present time, the department's list of licensed or registered child care facilities includes 44 sites with "preschool" in their title and all are eligible for review of immunization records. To supplement this effort, immunization contracts with local public health agencies will be revised in 2015 to request assistance with identifying and assessing preschools, if any, that are not presently licensed or registered as a child care facility.

Planned Completion Date: Revisions to the immunization contracts will be effective January 1, 2015.

Recommendation #3a: We recommend the Department of Public Health and Human Services: Expand contract provisions with the local health department to follow up on children reported as noncompliant or conditionally attending.

Response: Concur

Corrective Action: Department contracts and procedures issued in 2015 will be modified to improve documentation of outcomes of any child determined as noncompliant (not up to date) during an immunization review. Department immunization staff will work closely with staff of the Quality Assurance Division (QAD) to implement and promote a consistent approach to exclusion and documentation.

Children conditionally attending are technically in compliance and public health authorities may or may not be directly involved in each case. However, when attendees with conditional approvals are found during review, processes for additional follow-up will be developed and implemented during the 2015 contract period.

Planned Completion Date: Revisions to the immunization contracts will be effective January 1, 2015.

Recommendation #3b: We recommend the Department of Public Health and Human Services: Follow up with local health departments to ensure exclusions occur in compliance with immunization requirements.

Response: Concur

Corrective Action: None required. Department policies regarding exclusions have been developed and shared with all local public health jurisdictions and related trainings have, and will continue to be, conducted. In addition, many public health jurisdictions have exercised their local powers to exclude children not in compliance with administrative rules, in some cases going beyond department guidance. The department is confident that appropriate exclusions are occurring and efforts to improve overall documentation of child care immunization reviews in 2015 will provide more information exclusions that occur.

Planned Completion Date: Already in place

Recommendation #4: We recommend the Department of Public Health and Human Services strengthen its annual child care assessment selection process to ensure all facilities are consistently assessed.

Response: Concur

Corrective Action: The department works closely with local public health jurisdictions to assess compliance with immunization requirements in child care settings. Licensed centers, currently numbering 260, are reviewed annually in accordance with 52-2-733 MCA. The same statute requires 20% of the 825 registered facilities to be reviewed annually. State surveyors from QAD conduct the visits and perform inspections and immunization reviews in registered child care facilities. While state surveyors inspect licensed facilities, immunization reviews in these facilities are conducted by local health agencies. The department's immunization contracts with local public health jurisdictions were intended to supplement this process and ensure more frequent reviews of 825 registered facilities and better document reviews of the 260 licensed facilities. As a result, the department maintains that the current level of reviews is more than adequate and exceeds the oversight required by the statute.

However, the department does see the need to improve documentation of the processes and more frequent state-level review of inspections performed to ensure immunization audits occur as intended. To accomplish this task, the department will adapt the electronic system utilized by schools to capture, document and share information related to child care reviews. We anticipate implementing this system at the beginning of the 2015 contract period.

Planned Completion Date: Revisions to the immunization contracts will be effective January 1, 2015.

Recommendation #5a: We recommend the Department of Public Health and Human Services: Develop formalized policy and procedures regarding the compilation and verification of school reports.

Response: Concur

Corrective Action: Annual review and submission of information related to school immunization coverage levels is required by rule. Since implementation of electronic submittal of this information three years ago, we have a 92 to 95 percent compliance rate from the state's 824 (2013-14 Office of Public Instruction (OPI) listing) schools on our list. Policies and procedures for the submission of reports are in place; however, verification of the information submitted by schools is not currently conducted.

The department will work with local public health jurisdictions and program staff to develop a sampling approach to verify accuracy of reports. The focus of this effort will be restricted to kindergartens and 7th grade- key populations tracked at the federal level. Reviews will be documented and significant discrepancies may result in additional reviews and training of relevant staff. These efforts will be in place at the beginning of the 2014-15 school year.

Planned Completion Date: A system to verify a sample of selected grades will be implemented at the beginning of the 2014-15 school year

Recommendation #5b: We recommend the Department of Public Health and Human Services: Develop a documented process to actively monitor school attendee compliance with immunization requirements.

Response: Do not concur

Corrective Action: None. As stated in our response to recommendation #5a, administrative rules of the department require schools to submit annual reports regarding immunization of pupils. Reports are to be reviewed at the state and local level and actions taken if concerns are identified. The position of the department is that this approach is sufficient and consistent with statute. Statutes 20-5-403 through 408 MCA are clear that enforcement is the responsibility of each school. However, department communications with schools and local public health agencies prior to the 2014-15 school year will provide guidance on compliance issues and improving review of, and response to, school immunization reports at the local public health level.

Recommendation #6a: We recommend the Department of Public Health and Human Services develop a documented process to: Notify schools about the requirements of ARM 37.114.721.

Response: Concur

Corrective Action: The department communicates with all schools at the beginning of each school year regarding immunization reporting requirements. Education regarding ARM 37.114.721 requiring reporting of exclusions lasting 3 days or more to state and local public health will be provided. The department will provide guidance to local public health agencies regarding this rule and suggest steps they may take to address the issue. Communications and guidance regarding this will be disseminated to school administrators and public health officials at the beginning of the 2014-15 school year.

Planned Completion Date: Information regarding compliance with the above rule will be disseminated in September of the 2014-15 school year.

Recommendation #6b: We recommend the Department of Public Health and Human Services develop a documented process to: Track students excluded from failing to meet the requirements of a conditional enrollment.

Response: Concur

Corrective Action: Information submitted in response to ARM 37.114.721 requiring reporting of exclusions in schools lasting 3 days or more will be systematically documented at the state level. This will be implemented at the beginning of the 2014-15 school year.

Planned Completion Date: A system to track excluded students will be in place at the beginning of the 2014-15 school year.

Recommendation #7: We recommend the Department of Public Health and Human Services seek legislation providing guidance on the use of the state's immunization registry.

Response: Concur

Corrective Action: The department is currently reviewing options to address a number of immunization related issues, including simplifying use of the state's immunization information system (IIS). Specifically, implementing an approach that would include all vaccine recipients unless they have chosen to opt-out is being considered. Opt-out approaches allow for more efficient operations at the patient, provider and state level while still allowing personal choice. At the present time, Montana is one of three states with an opt-in approach which adds cost and complexity to the operation of local and state systems.

Planned Completion Date: Potential legislation may be prepared during the 2015 legislative session. Final results are legislature dependent.

Recommendation #8a: We recommend the Department of Public Health and Human Services: Develop written procedures and mappings for data flow into the immunization registry.

Response: Concur

Corrective Action: None required. Documentation regarding mapping of data elements in the IIS have been developed and distributed. At the present time 25 facilities are submitting data electronically to the IIS- each following the data formats specified by the department's immunization program. Additional sites are in the planning or testing process. In addition to electronic transfer, IIS documentation details hand entry of data as well

Planned Completion Date: Already in place

Recommendation #8b: We recommend the Department of Public Health and Human Services: Determine what validations are applied to the data and document the findings.

Response: Concur

Corrective Action: The IIS acquired by the department is based on architecture that was originally developed in Wisconsin and modified by other states as immunization recommendations and methods of data transfer evolved. The department acknowledges that certain algorithms used by the software lack detailed documentation. The department is committed to continuing our efforts to work with the assistance of our vendor to document details of the algorithm.

Planned Completion Date: This is an ongoing process and no specific time frame has been developed.

Recommendation #9a: We recommend the Department of Public Health and Human Services: Create applications roles that limit permissions assigned to only those required for the specific position.

Response: Concur

Corrective Action: The department has reviewed the 34 accounts identified by the audit and has been able to reduce the number to 24 accounts necessary for operations. Many of the extra accounts were used for testing purposes or one-time events and were no longer necessary. Existing accounts will be reviewed at least twice annually to ensure that any account no longer needed is deleted from the system.

Planned Completion Date: Already in place

Recommendation #9b: We recommend the Department of Public Health and Human Services: Limit contractor access to production data.

Response: Concur

Corrective Action: None required. The department's contractor is essential to operation of the IIS and access is already limited to essential staff. The department will continue to monitor access as part of our biannual review process and continue to ensure only essential staff have access to production data.

Planned Completion Date: Already in place

Recommendation #10: We recommend the Department of Public Health and Human Services develop and implement documented procedures for monitoring activity of users with privileged roles.

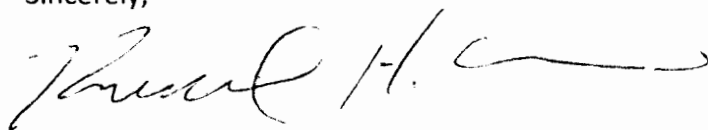
Response: Concur

Corrective Action: Procedures will be developed and reviewed with users with privileged roles regarding system use. However, at the present time the vast majority of users, including privileged users, can change patient data and such abilities are a must for function of the registry. It is important to note that average and privileged users cannot change tables or other items involved in set-up of the registry. Privileged users can view more detailed patient information. Such access is necessary during public health events to determine who may be at risk or protected when a vaccine preventable disease is involved.

Planned Completion Date: Anticipated to be developed and distributed by June 30th, 2014.

Thank you for the detailed examination of our immunization efforts and the valuable insight.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard H. Opper", with a long horizontal flourish extending to the right.

Richard H. Opper
Director

cc: Marie Matthews, Operations Services Branch Manager
Becky Schlauch, Business and Financial Services Division Administrator
Jim Murphy, Communicable Disease Control & Prevention Bureau Chief